

## Accelerating Center

### RFA INFR 1: Partnering Opportunity to Create a CIRM Accelerating Center

#### Objective

The mission of California Institute for Regenerative Medicine (CIRM) is to accelerate stem cell treatments to patients with unmet medical needs.

The objective of this partnering opportunity is to create the CIRM Accelerating Center, a top quality clinical research organization (CRO) with a dedicated focus on stem cell treatments. Operating from a facility permanently located within California, the Accelerating Center will provide regulatory, operational and consultative services to clinical trial sponsors in order to accelerate the regulatory review process and the conduct of high quality clinical trials using stem cell treatments. The Accelerating Center will initially focus on CIRM-funded projects<sup>1</sup>, but must include a business plan to extend the services to other clients so as to ensure Center sustainability.

The Accelerating Center is one of multiple coordinated Infrastructure Programs that CIRM is establishing to overcome obstacles and accelerate the progression of stem cell treatments through translational, preclinical, and clinical research to demonstrate clinical proof of concept.<sup>2</sup> Other Infrastructure Programs include the CIRM Translating Center and the CIRM Alpha Clinics Network.

The CIRM Translating Center is a stem cell preclinical research organization that will be launched later this year. The Translating Center will support process development, manufacturing, and preclinical research activities that are necessary to support regulatory filings (e.g., Investigational New Drug Applications (IND) with the Food & Drug Administration (FDA)). The Accelerating Center will develop service contracts with the Translating Center and act as the lead organization in interactions with the FDA in support of regulatory submissions. The existing Alpha Clinics Network provides clinical trial sites and Accelerating and Value Add Resources (AVARs). The Accelerating Center will facilitate utilization of the Alpha Clinics Network by aiding the conduct of clinical trials, by bringing additional trials to the network, and by facilitating use of the (AVARs). Together, these CIRM Infrastructure Programs will support CIRM-funded translational, preclinical, and clinical projects to develop stem cell treatments for patients with unmet medical needs.

These centers are intended to address common concerns raised by both researchers and regulatory officials, making them particularly valuable tools to increase the quality and speed of clinical and translational stage projects.

- **INFR1: Partnering Opportunity to Create a CIRM Accelerating Center** (updated 3.1.16)
- Appendix A: Sample Accelerating and Value Added Resources (AVARs) for the Alpha Stem Cell Clinic Network
- INFR1: Accelerating Center Background Presentation
- INFR1: Frequently Asked Questions & CIRM Responses (updated 4.11.16)

#### To Submit an Application:

1. Go to the **Grants Management Portal** (<https://grants.cirm.ca.gov>) and log in with your existing CIRM Username and Password. If you do not have a Username, Click on the **"New User"** link and follow the instructions to create a CIRM Username and password.
2. After logging in, Click on the Menu tab. Select the tab labeled **"Open Programs"**. Under the section labeled **"RFAs and Programs Open for Applications"**, click on the **"Start a Grant Application"** link for your selected program.
3. Complete each section of the Application by clicking on the appropriate link and following the posted instructions. Proposal templates can be located and submitted under the **"Uploads"** section.
4. To submit your Application, click on the **"Done with Application"** button. The **"Done with Application"** button will be enabled when all of the mandatory sections have been completed. Please note that once this has been selected, you will no longer be able to make changes to your Application.
5. To confirm submission of your Application, select the tab labeled **"Your Applications"** and check the table under the section labeled **"Your Submitted Applications"**. You will see your Application number and project title listed once the submission process has been completed.

**ICOC approval:**

Jun 15, 2016

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